AN ACT concerning pharmaceuticals.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Pharmacy Practice Act of 1987 is amended by changing Section 25 as follows:

(225 ILCS 85/25) (from Ch. 111, par. 4145)

Sec. 25. No person shall compound, or sell or offer for sale, or cause to be compounded, sold or offered for sale any medicine or preparation under or by a name recognized in the United States Pharmacopoeia National Formulary, for internal or external use, which differs from the standard of strength, quality or purity as determined by the test laid down in the United States Pharmacopoeia National Formulary official at the time of such compounding, sale or offering for sale. Nor shall any person compound, sell or offer for sale, or cause to be compounded, sold, or offered for sale, any drug, medicine, poison, chemical or pharmaceutical preparation, the strength or purity of which shall fall below the professed standard of strength or purity under which it is sold. If the physician or other authorized prescriber, when transmitting an oral or written prescription, does not prohibit drug product selection, a different brand name or nonbrand name drug product of the same generic name may be dispensed by the pharmacist, provided that the selected drug has a unit price less than the drug product specified in the prescription and provided that the selection is permitted, is not subject to <u>review at a meeting of</u> ~~a--hearing--by~~ the Technical Advisory Council, <u>is not subject to a hearing in accordance with this Section,</u> or is not specifically prohibited by the current Drug Product Selection Formulary issued by the Department of Public Health pursuant to Section

3.14 of the Illinois Food, Drug and Cosmetics Act, as amended. A generic drug determined to be therapeutically equivalent by the United States Food and Drug Administration (FDA) shall be available for substitution in Illinois in accordance with this Act and the Illinois Food, Drug and Cosmetic Act, provided that each manufacturer submits a notification containing product technical bioequivalence information as a prerequisite to product substitution when they have completed all required testing to support FDA product approval and, in any event, the information shall be submitted no later than 60 days prior to product substitution in the State. If the Technical Advisory Council finds that a generic drug product may have issues related to the practice of medicine or the practice of pharmacy, the Technical Advisory Council shall review the generic drug product ~~hold a hearing~~ at its next regularly scheduled Technical Advisory Council meeting. Following the Technical Advisory Council's review and initial recommendation that a generic drug product not be included in the Illinois Formulary, a ~~determination that an issue exists related to the practice of medicine or the practice of pharmacy, the~~ hearing shall be conducted in accordance with the rules of the Department of Public Health and Article 10 of the Illinois Administrative Procedure Act if requested by the manufacturer. The Technical Advisory Council shall make its recommendation to the Department of Public Health within 20 business days after the public hearing. If the Department of Public Health, on the recommendation of the Technical Advisory Council, determines that, based upon a preponderance of the evidence, the drug is not bioequivalent, not therapeutically equivalent, or could cause clinically significant harm to the health or safety of patients receiving that generic drug, the Department of Public Health may prohibit the generic drug from substitution in the State. A decision by the Department of Public Health

to prohibit a drug product from substitution shall constitute a final administrative decision within the meaning of Section 22.2 of the Illinois Food, Drug and Cosmetic Act and Section 3-101 of the Code of Civil Procedure, and shall be subject to judicial review pursuant to the provisions of Article III of the Administrative Review Law. A decision to prohibit a generic drug from substitution must be accompanied by a written detailed explanation of the basis for the decision. On the prescription forms of prescribers, shall be placed a signature line and the words "may substitute" and "may not substitute". The prescriber, in his or her own handwriting, shall place a mark beside either the "may substitute" or "may not substitute" alternatives to guide the pharmacist in the dispensing of the prescription. A prescriber placing a mark beside the "may substitute" alternative or failing in his or her own handwriting to place a mark beside either alternative authorizes drug product selection in accordance with this Act. Preprinted or rubber stamped marks, or other deviations from the above prescription format shall not be permitted. The prescriber shall sign the form in his or her own handwriting to authorize the issuance of the prescription. When a person presents a prescription to be dispensed, the pharmacist to whom it is presented may inform the person if the pharmacy has available a different brand name or nonbrand name of the same generic drug prescribed and the price of the different brand name or nonbrand name of the drug product. If the person presenting the prescription is the one to whom the drug is to be administered, the pharmacist may dispense the prescription with the brand prescribed or a different brand name or nonbrand name product of the same generic name that has been permitted by the Department of Public Health, if the drug is of lesser unit cost and the patient is informed and agrees to the selection and the pharmacist shall enter such information into the pharmacy record. If the

person presenting the prescription is someone other than the one to whom the drug is to be administered the pharmacist shall not dispense the prescription with a brand other than the one specified in the prescription unless the pharmacist has the written or oral authorization to select brands from the person to whom the drug is to be administered or a parent, legal guardian or spouse of that person.

In every case in which a selection is made as permitted by the Illinois Food, Drug and Cosmetic Act, the pharmacist shall indicate on the pharmacy record of the filled prescription the name or other identification of the manufacturer of the drug which has been dispensed.

The selection of any drug product by a pharmacist shall not constitute evidence of negligence if the selected nonlegend drug product was of the same dosage form and each of its active ingredients did not vary by more than 1 percent from the active ingredients of the prescribed, brand name, nonlegend drug product or if the selected legend drug product was included in the Illinois Drug Product Selection Formulary current at the time the prescription was dispensed. Failure of a prescribing physician to specify that drug product selection is prohibited does not constitute evidence of negligence unless that practitioner has reasonable cause to believe that the health condition of the patient for whom the physician is prescribing warrants the use of the brand name drug product and not another.

The Department is authorized to employ an analyst or chemist of recognized or approved standing whose duty it shall be to examine into any claimed adulteration, illegal substitution, improper selection, alteration, or other violation hereof, and report the result of his investigation, and if such report justify such action the Department shall cause the offender to be prosecuted.

(Source: P.A. 91-766, eff. 9-1-00.)

Section 10. The Illinois Food, Drug and Cosmetic Act is amended by changing Section 3.14 as follows:

(410 ILCS 620/3.14) (from Ch. 56 1/2, par. 503.14)

Sec. 3.14. Dispensing or causing to be dispensed a different drug in place of the drug or brand of drug ordered or prescribed without the express permission of the person ordering or prescribing. However, this Section does not prohibit the interchange of different brands of the same generically equivalent drug product, when the drug products are not required to bear the legend "Caution: Federal law prohibits dispensing without prescription", provided that the same dosage form is dispensed and there is no greater than 1% variance in the stated amount of each active ingredient of the drug products. Nothing in this Section shall prohibit the selection of different brands of the same generic drug, based upon a drug formulary listing which is developed, maintained, and issued by the Department of Public Health under which drug product selection is permitted, is not subject to review at a meeting of ~~the hearing review process by~~ the Technical Advisory Council, is not subject to a hearing in accordance with this Section, or is not specifically prohibited. A generic drug determined to be therapeutically equivalent by the United States Food and Drug Administration (FDA) shall be available for substitution in Illinois in accordance with this Act and the Pharmacy Practice Act of 1987, provided that each manufacturer submits a notification containing product technical bioequivalence information as a prerequisite to product substitution when they have completed all required testing to support FDA product approval and, in any event, the information shall be submitted no later than 60 days prior to product substitution in the State. If the Technical Advisory Council finds that a generic drug product may have issues related to the practice of medicine or the practice of

pharmacy, the Technical Advisory Council shall review the generic drug product ~~hold-a-hearing~~ at its next regularly scheduled Technical Advisory Council meeting. Following the Technical Advisory Council's review and initial recommendation that a generic drug product not be included in the Illinois Formulary, a ~~determination-that-an-issue-exists related-to-the--practice--of--medicine--or--the--practice--of pharmacy,--the~~ hearing shall be conducted in accordance with the Department's Rules of Practice and Procedure in Administrative Hearings (77 Ill. Admin. Code 100) and Article 10 of the Illinois Administrative Procedure Act if requested by the manufacturer. The Technical Advisory Council shall make its recommendation to the Department of Public Health within 20 business days after the public hearing. If the Department of Public Health, on the recommendation of the Technical Advisory Council, determines that, based upon a preponderance of the evidence, the drug is not bioequivalent, not therapeutically equivalent, or could cause clinically significant harm to the health or safety of patients receiving that generic drug, the Department of Public Health may prohibit the generic drug from substitution in the State. A decision by the Department to prohibit a drug product from substitution shall constitute a final administrative decision within the meaning of Section 22.2 of the Illinois Food, Drug and Cosmetic Act and Section 3-101 of the Code of Civil Procedure, and shall be subject to judicial review pursuant to the provisions of Article III of the Administrative Review Law. A decision to prohibit a generic drug from substitution must be accompanied by a written detailed explanation of the basis for the decision. Determination of products which may be selected shall be recommended by a Technical Advisory Council of the Department, selected by the Director of Public Health, which council shall consist of 7 persons including 2 physicians, 2 pharmacists, 2 pharmacologists and one other

prescriber who have special knowledge of generic drugs and formulary. Technical Advisory Council members shall serve without pay, and shall be appointed for a 3 year term and until their successors are appointed and qualified. The procedures for operation of the Drug Product Selection Program shall be promulgated by the Director, however the actual list of products prohibited or approved for drug product selection need not be promulgated. The Technical Advisory Council shall take cognizance of federal studies, the U.S. Pharmacopoeia - National Formulary, or other recognized authoritative sources, and shall advise the Director of any necessary modifications. Drug products previously approved by the Technical Advisory Council for generic interchange may be substituted in the State of Illinois without further review subject to the conditions of approval in the State of Illinois prior to the effective date of this amendatory Act of the 91st General Assembly.

Timely notice of revisions to the formulary shall be furnished at no charge to all pharmacies by the Department. Single copies of the drug formulary shall be made available at no charge upon request to licensed prescribers, student pharmacists, and pharmacists practicing pharmacy in this State under a reciprocal license. The Department shall offer subscriptions to the drug formulary and its revisions to other interested parties at a reasonable charge to be established by rule. Before the Department makes effective any additions to or deletions from the procedures for operation of the Drug Product Selection Program under this Section, the Department shall file proposed rules to amend the procedures for operation of the program under Section 5-40 of the Illinois Administrative Procedure Act. The Department shall issue necessary rules and regulations for the implementation of this Section.

(Source: P.A. 91-766, eff. 9-1-00.)

Section 99. Effective date. This Act takes effect upon becoming law.